August 20, 1999

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: 99P-1340/CP 1

Petition to Have "Eternity eau de parfum" Misbranded

Overview

I am expressing my whole-hearted support for the petition submitted in May of this year by the Environmental Health Network (EHN) to have Calvin Klein's "Eternity eau de parfum" declared misbranded, based on FDA regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10.

My support for this petition is specifically based on the portion of regulation 21CFR Sec. 740.10, which states:

"Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: "Warning—The safety of this product has not been determined."

The EHN petition shows that "Eternity" contains toxic ingredients, and ingredients whose safety has not been substantiated, and also that its packaging does not contain the requisite warning label.

I personally am not chemically sensitive, but my wife is. When she is exposed to "Eternity" or other fragrances, she experiences pain in her nostrils and sinuses, immediate headache, sudden fatigue, and a steep decline in her mental functioning (including short term memory and the ability to process information and express herself). I would say that any substance causing symptoms like these deserves a warning label.

Conclusion

Not properly labeling products that contain known toxic ingredients is a serious public health issue. Although some people do not currently react to the toxic ingredients in products like "Eternity", the FDA (not to mention the EPA) knows that these ingredients are dangerous. And when it comes to perfume, no one knows how much is "too much". At the very least, the public has a right to know what is in the products they purchase, and the manufacturers of those products have a duty to provide that information. I ask that your office follow its own mandate and, in that regard, carefully consider the EHN petition to misbrand "Eternity" and thereby help protect us all.

Sincerely,

C290

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